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(54) Method and apparatus for removal of osteal prostheses.

(57) A relatively massive annular body (10) is driven in radial mode resonant oscillation by an ultrasonic driver (20) that is fixed to the periphery of the annular body (10), with the axis (21) of its ultrasonic drive oriented for intersection with the central axis of the annular body (10). A selectable chucking device (12) within the bore of the annular body is adapted to engage part of a prosthetic device (19), to which the resonant oscillation is imparted, for melting surrounding bone cement and for severing body ingrowth into the prosthetic, thus permitting retraction of the prosthetic from its pre-existing implantation in a living bone.

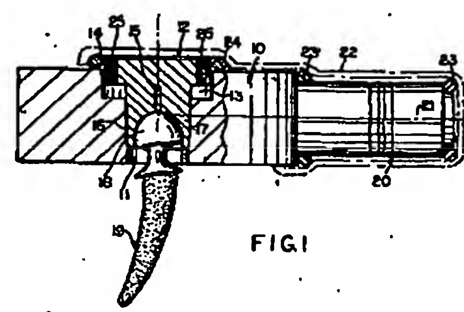

FIG.1

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The invention relates to an ultrasonic method and means for removing an osteal prosthesis from cemented installation in a living bone, as in the course of revision arthroplasty.

It is known from U.S. Patents 4,248,232 and 5,151,099 that ultrasound may be used to facilitate removal of bone cement (PMMA) during revision arthroplasty. Local heating, by preferential absorption of ultrasound energy, raises the temperature of a small volume of the cement above the glass-transition temperature, thus allowing the cement to flow and to be manipulated into a shape and form which may be readily removed from the revision site.

It has also been claimed (Hood, et al., U.S. Patent 5,045,054) that the application of ultrasound directly to the prosthesis can break the bond between the prosthesis and surrounding cement or, in the case of uncemented prostheses, between the prosthesis and in-grown cancellous bone. The direction of applied ultrasonic energy is in line with the central axis of an implanted prosthetic device, such as the axis of stem support for the ball of a hip-joint replacement. But the in-line application of force, as in the context of the Hood, et al. system, is to require the patient to oppose the force, with inevitable trauma for the patient.

It is an object of the invention to provide an improved method and means for dislodging an installed osteal prosthesis with a minimum of trauma for the patient who is faced with the need of revision arthroplasty.

A specific object is to meet the above object for the case of revision arthroplasty of a hip-joint prosthesis that has been implanted and cemented in a femur.

It is a general object to meet the above objects with a method and apparatus of reliably high performance without a daunting level of operating complexity, which method and apparatus are applicable to the full variety of currently available prostheses.

The invention in its preferred embodiment meets these objects in an ultrasonically driven technique wherein an annular body of relatively great mass is solidly chucked around the exposed proximal end of a hip-joint prosthesis which has been cemented in the medullary canal of a femur. In most cases, the exposed proximal end is a sphere or ball at the projecting end of a stem, all integrally formed with the implanted remainder of the prosthetic device. The annular body is excited into ultrasonic radial-mode oscillation by a driver having a directional axis of mechanical oscillation, wherein the said axis is preferably radially inward through body material, toward the body axis, and preferably for substantial alignment with the center of the exposed ball or head end of the prosthesis to be removed, as for prosthetic replacement in the patient. In response to such excitation, the annular body reacts with radial-mode resonant oscillation, involving circumferentially continuous application of radially modulated squeezing transfer of ultrasonic energy into the prosthetic at the region of chucked engagement; and, in turn, the prosthetic responds to the radial-mode resonance by such plastic-deformation of its cemented and/or bony-ingrowth attachment to the patient's limb, as to locally generate enough heat to melt cementing plastic at interface with the prosthetic, or to mechanically sever bony ingrowth at interface with the prosthetic. The ultrasonically driven body annulus is of such design as to selectively accommodate a variety of sizes of prosthetic-head chucked engagement; The body annulus will also accommodate a special tool which may be selected from one of a group of chucks, each of which is configured to coupling to the buried end of a broken fragment of a prosthetic shaft, with an ability to transfer sufficient ultrasonic energy through the tool and into the broken and buried prosthetic fragment, for clean and efficient dislodging and extraction of the buried fragment.

Embodiments of the present invention will now be more particularly described by way of example and with reference to the accompanying drawings, in which:

Fig. 1 is view in side elevation, partly broken-away and in section, to show elements of a prosthetic-removal device of the invention;

Fig. 2 is a view similar to Fig. 1 to show a modification;

Fig. 3 is an exploded view of separable parts, as in Fig. 2;

Fig. 4 is a plan view of the device of Fig. 3;

Fig. 5 is a view similar to Fig. 1 to show another modification;

Fig. 6 is a view similar to Fig. 1 to show a further modification;

Fig. 7 is a view in longitudinal section of a tool element usable in conjunction with any of the devices of Figs. 1, 2, 3, 5 or 6, for removal of a distal broken end of prosthetic device;

Fig. 8 is a sectional view to show use of the tool of Fig. 7 in the device of Fig. 6;

Fig. 9 is an electrical block diagram to show excitation and control circuitry for use in any of the disclosed prosthetic-removal embodiments of the invention;

Fig. 10 is a graph to illustrate a frequency band characteristic of ultrasonic operation, using circuitry of Fig. 9;

Fig. 11 is a front elevation of a tool element for removing small quantities of cement;

Fig. 12 is a side elevation of the tool element shown in Fig 11; and

Fig. 13 is a plan view of the tool shown in Figs 11 & 12.

Referring initially to Fig. 1, the invention is shown in application to a radial-mode oscillator comprising an annular body 10 of relatively great mass, suitably

of stainless steel. Body 10 is of generally right-cylindrical configuration and has a central bore 11 which is slightly convergent in the downward direction, for the purpose of coaction with a chuck or collet member 12. At its upper end, bore 11 expands via a counterbore 13 which will accommodate the radially flanged head end 14 of member 12.

The chuck or collet member 12 has a reduced distally extending lower end which is longitudinally split, as at slit 15, to define plural distal fingers, here shown as the two fingers 16, 17, in view of the single slit 15.

In the case of Fig. 1, the exposed spherical head or ball 18 of an installed hip prosthesis 19 is securely engaged by concave spherical formations within the distal or finger end of member 12, i.e., within confronting internal concave spherical surfaces of the two fingers 16, 17, it being understood that the concavities of fingers 16, 17 cooperatively define a hemispherical socket against which a ball head 18 intimately nests. The external surfaces of fingers 16, 17 preferably conform to convergence of the body bore 11 such that, once the ball head 18 has been inserted into the unstressed socket defined by the internal concave spherical surfaces of fingers 16, 17, the collet or chuck member 12 may be driven downward to securely and circumferentially continuously engage and grip the ball head 18. The drive to establish such a grip can be obtained by hammer blows delivered axially to the flanged upper end 14; in the course of such a drive, fingers 16, 17 are inwardly deflected by wedge action between the convergent concave and convex tapering surfaces, and it will be understood that in a finally chucked position, as in Fig. 1, the ball head 18 not only has virtually equatorial grip by the fingers 16, 17, but that this grip is similarly circumferential for axially extending areas above and below the equatorial location. Alternatively, the surgeon may be of the view of hammer blows might result in trauma to the patient, in which case a pair of opposed C-clamps applied to squeeze the flange of member 12 with respect to the lower annular surface of body 10 is indicated, for a reduced likelihood of trauma.

To excite the described body 10 and its securely chucked prosthetic device 19, an electromechanical transducer 20 is shown secured locally to the periphery of body 10. Transducer 20 is suitably of the piezoelectric ceramic variety generally as shown and described (at reference number 1) in U.S. Patent 5,151,099 and in pending application Serial No. 08/199,112, filed February 22, 1994, to which reference is made for greater detail. Transducer 20 is cylindrical and has a central axis 21 of mechanically resonant oscillation, at a frequency in the range 20 kHz to 40 kHz. The transducer is driven as the electrical load of circuitry to be described later in connection with Fig. 9, but which will be indicated here to feature a phase-locked loop for automatic High-Q tuning over a range of frequencies. The range of frequency adjustment will be understood to be that which best serves the mechanically resonant properties of body 10 and its well chucked connection to prosthetic 19, and the latter will be further understood to be in its embedded condition, and to have been the subject of an arthroscopic femoral procedure which now requires replacement.

To give an indication of size, a radial-mode resonant body 10 to accommodate a ball head 18 of 1-inch diameter is suitably of 5 to 6 inches diameter, with an axial. thickness of two inches; and transducer 20 may suitably be of 3 to 3.5 inches overall length and 1 to 1.6 inches diameter.

A housing recommended for the described parts may generally be as shown and described in pending patent application Serial No. 08/199,112, as long as the housing enables safe handling during ultrasonic operation. The phantom outline 22, with elastomeric O-ring supports at 23, 23', 24 will be understood to be suggestive of such a housing. The housing 22 happens to be removable, cylindrically surrounding the transducer 20 and thus providing a handle that is mechanically insulated from transducer resonance, and with an upper looping ring portion removably centered on and surrounding the flanged upper end of the chuck or collet member 12.

In operation, excitation of transducer 20 induces radial-mode resonance in body 10 and in the chuck and ball-head elements securely bound within body 10. The ball-head is thus induced to track the excursions of this mechanical resonance and to couple them into the volume of the prosthetic 19, with resultant complex mechanical oscillation (featuring multiple nodes/antinodes) at interface between the shank of the prosthetic and such plastic cement or other bond (such as bony ingrowth) that may exist. The result is rapidly, within seconds, to melt cement and to shear bony ingrowth and thus to enable manual retraction of the radial-mode system and the prosthetic 19.

In the course of such retraction, which can be relatively quickly accomplished (in view of the tapered nature of the embedded prosthetic stem), it is optional whether or not the transducer remains excited, because the embedment bond to the patient will have been severed.

A note should be made to the effect that the prosthetic appliance 19 shown for illustration herein is an integrally formed single piece, so that a dislodgement is of the entire appliance. There are, however, other appliance structures in use for the same kind of hip-joint replacement. For example, the ball head 18 may have been a separately manufactured ball having a radial bore for "permanent" Morse-taper fit to an otherwise exposed stud which is an integral part of the prosthetic. In that event, the described ultrasonic radial-mode excitation of the exposed ball of the prosthetic appliance may result in dislodging the ball from

its Morse-taper fit, thus exposing the tapered stud portion of an appliance that remains embedded in the patient. For such a situation, it will be understood that a second radial-mode system as described for Fig. 1 may be at hand and equipped with a chuck or collet having internal concave contours suited for axially extensive and for virtually circumferentially continuous engagement with the otherwise exposed stud end of the prosthetic. Ultrasonic excitation of the chucked stud will then achieve the same desired result of inducing such mechanical action at the embedded interface or interfaces within the body as to enable quick and efficient retraction of the prosthetic.

Once the prosthetic has been removed, personnel aiding the surgeon can address the problem of disengaging the chuck and the chucked prosthetic from the radial-mode body. To this end, angularly spaced plural tapped bores 25 in the flanged end of the chuck may be threaded with bolts (not shown), for axially jacking reference to the flat inner annular end of the counterbore 13. Upon a sufficiently jacked displacement, the chuck action becomes dislodged and the prosthetic and the chuck 12 may be removed from each other and from body 10.

The embodiment of Fig. 2 represents slight modification from what has been described for Fig. 1, and the same reference numbers are re-used where possible. The chief difference in Fig. 2 is that the directional axis 21' of ultrasonic excitation by transducer 20 is not only oriented radially inward, but axis 21' is also inclined downwardly for intersection at or near the spherical center of the concave spherical inner surfaces of fingers 16, 17, thus at or near the spherical center of a ball or ball head 18 chucked thereto. To this end, the annular body 10' for excitation into radial-mode mechanical oscillation has an outer surface 27 which is frusto-conical so that the inclined driving end face of transducer 20 may be mounted to a locally milled flat 27' in the frusto-conical outer surface. Further, Fig. 2 shows an additional counterbore 28 at the lower end of the central bore of body 10, to provide greater concentration of ultrasonic energy from body 10' structure to an exposed ball head and an associated bone structure (not shown in Fig 2).

Figs. 3 and 4 depict in greater detail an alternative version of the modification of Fig. 2, wherein the axial direction 21' of ultrasonic excitation from transducer 20 into body 10 is again radially inward and also downwardly tilted for anticipated near-center delivery to the spherical center of a chucked ball head 18. In Fig. 3, body 10 is again cylindrically annular as in Fig. 1, and the driving end of transducer 20 is received in a shallow, suitably inclined local bore in the periphery of body 10, for flat-to-flat end-face delivery of mechanical oscillation to body 10; in Fig. 3, a reduced stud portion 30 of the driving end face of the transducer is shown in tightly threaded engagement with a tapped bore at the base of the transducer-seating bore in body 10.

The greater detail of Fig. 3 enables identification of further features common to all embodiments of the present invention. The threaded mounting via a stud is at 30, with otherwise flat-to-flat end interface from the transducer to the radial-mode body; such a flat-to-flat interface can be taken as presently preferred for all embodiments. The length L of the transducer should be integer number of half-wavelengths of sound transmission in the medium of the transducer; this medium is preferably a conventional sandwich of aluminium alloy and stainless steel plate elements except of course for the piezo-electric ceramic disc and its wafer-thin electrodes which are at an outward offset from a central transverse plane of the transducer. The mean diameter $D_{\square}$ of the radial-mode body 10 is preferably such as to account for a mean geometrically circumferential extent (i.e., at diameter $D_{\square}$) which is approximately an integer multiple of said wavelength. And the slightly convergent taper angle α within the bore of body 10 is preferably in the range 1° to 2°. Anticipating substantial spherical concave-to-convex surface light engagement of the chuck or collet fingers 16, 17 to the ball or ball head 18, the concave spherical surfaces of fingers 16, 17 are preferably generated when fingers 16, 17 are radially inwardly displaced to the extent of an ultimately chucked state; and the outer-surface contouring of the chuck fingers 16, 17 is such as to develop progressive inwardly cantilevered bending to lock onto a ball or ball head 18 in the course of hammering or other axially jacked displacement into the fully chucked position shown for all embodiments except for the exploded diagram of Fig. 3.

Finally, Fig. 3 illustrates the environment for use of a radial-mode system for all embodiments of the invention, namely, that the tapered stem portion 31 of the involved prosthetic device 19 has the environment of plastic cement 32, securing the prosthetic to and with an intramedullary cavity in a suitably cored and otherwise prepared proximal end of a femur 33. The relatively massive use of plastic cement 32 shown in Fig 3 will be understood to have been exaggerated, and it will be understood that very often in the preparation of a femur to receive a hip-joint prosthetic 19, the stem 31 will have been installed at least in part in such direct adjacency to bone tissue as to have involved bony-ingrowth into the prosthetic.

In the case of uncemented arthroplasty, the prosthesis will be attached by bone ingrowth and such attachment will be loosened or broken by relative vibrational movement at the bone/metal interface.

In the embodiment of Fig. 5, the radial-mode body 10 is right-cylindrical and of axial thickness matching the diameter of the transducer 20. There is no counterbore into which the flanged head of chuck 12 may be accommodated (as at 13 in Figs 1, 2 and 3); but there is a lower counterbore 28 which enables

clearance for chucked clamping of a prosthetic ball or ball head 18 with its spherical center substantially on the strictly radial transducer axis 21 of ultrasonic mechanical oscillation. Dimensioning applied to Fig. 5 identifies the cylindrical outer diameter D of body 10 and the mean diameter D_m. Further dimensioning at Δ identifies the fact that the body cylinder of diameter D is locally milled to a chordal flat (of radial depth Δ) for establishing a flat interface between transducer 20 and body 10, the same being tightly secured by threaded means 30.

The embodiment of Fig. 6 illustrates that a radial-mode annular body 40 of the invention need not be geometrically cylindrical, and it also illustrates that plural ultrasonic transducers may be provided at angular spacing around body 40, all with their respective axes of mechanical oscillation directed to substantially the center of a ball or ball head 18 of an implanted prosthetic 19. As shown, the plurality of transducers is two, at 180° spacing about the central axis of body 40. The geometry of body 40 may be described as annular, with a central bore and chucking or collet means 12 as previously described. The annular body 40 features an upper concave frusto-conical end face 41 that is axially spaced from a lower convex frusto-conical end face 42. The outer surface of body 40 is also frustoconical except for local chordal flats 43a, 43b to accept the flat-interface relation of transducers 20a, 20b at their respective connections to body 40. Preferably, the concave slope of upper surface 41 is at greater offset from a radial plane with respect to the central axis of body 40 than is the lesser such offset in the case of lower surface 42. This relationship establishes the presently preferred shape of body 40 as a dish wherein axial thickness reduces in approach to the central bore to which the chuck 12 is fitted, thus enabling radial-mode oscillation to bring resonant energy to even greater convergence at the desired locus of energy transfer to prosthetic 19. For purposes of deriving purely axial jacking force to dislodge a clamped condition of chuck 12, a small local fillet 44, one for each of the threaded jack bores 25 of the chuck flange, enables inserted jack bolts to be driven perpendicular to corresponding fillets 44.

In the removal or attempted removal of a hip-joint or other prosthetic from a patient, it sometimes happens that the stem of the prosthetic breaks or is found to have been broken, thus leaving a distally embedded fragment of the stem, as shown at 50 in Fig.8. At the point in time illustrated by Fig. 8, it will be understood that bone cement within the proximal end of a femur 52 has been selectively removed to establish an enlarged opening 53, i.e., enlarged from the socket of bone cement left upon removal of the proximal part of the prosthetic, and it will be further understood that this enlargement has been achieved not only as far as the embedded broken piece 50 but also to the extent $\underline{d_1}$ therebeyond. Bone-cement removal tooling as described in copending patent application Serial No. 08/199,112, filed February 22, 1994 is ideal for rapid and effective bone-cement removal to achieve the described enlargement, including to the predetermined depth $\underline{d_1}$ beyond the location of the break which produced the embedded fragment 50.

A tool 80 based on the technology described in the above mentioned patent application is shown in Figs 11 and 12. A claw probe attachment 81 may be used to melt and extract the cement in small quantities around the periphery of the end of the fragment to provide the enlarged opening 53. The tool comprises a stem 82 having at its distal end a small saucer shaped cup 81, having apertures 83 therethrough, though which cement melted by ultrasonic vibration of the cup 81, driven through the stem 82, may pass. The tool can be withdrawn periodically to extract cement or other material and thereby to form the enlarged opening. In this way, it functions as a scraper to provide or enlarge a space allowing engagement of an end of the broken prosthesis by the extraction tool. Providing space allows, a tool having a larger spoon shaped end may be inserted alongside the prosthesis to engage beneath its distal end.

Having thus prepared the enlargement 53 in bone cement at the proximal end of femur 52, and to the depth $\underline{d_1}$ beyond the break responsible for the embedded fragment 50, all is in readiness for use of a special tool bit as shown in Fig. 7, as a replacement for the chuck or collet element 12 in any of the embodiments described in connection with Figs. 1, 2, 3, 5, and 6 above; and in Fig. 8, the tool bit of Fig. 7 will be recognized in substitution for the chuck 12 of Fig. 6.

Briefly, the tool bit of Fig. 7 is suitably of stainless steel and comprises a flanged head 55, integrally formed with plural elongate, relatively massive but tweezer like, legs 56, 57. The outer diameter D_2 may be cylindrical and thus constant in manufacture of the tool bit. Within this cylindrical outer-surface profile, a gradually tapering bore establishes concave inner-surfaces 56', 57' of the legs 56, 57, all except for the distal remainder d_2 which is characterised by short distally convergent concave profiles 56", 57" within the distal ends of legs 56, 57. The cylindrical diameter D_2 is selected to permit insertional entry of the distal ends of legs 56, 57 through the upper end of the convergent central bore of the radial-mode body, the same to be inwardly cammed in the course of full insertion through this central bore. This inward canning action deflects legs 56, 57 toward each other and in all likelihood into radially loaded mutual contact of their distal ends by the time these distal ends have been extended substantially fully beyond passage through the bore of body 40. At this point it is a simple matter to compliantly spread apart the distal ends of legs 56, 57, as by inserting and twisting a screwdriver blade therebetween, the thus achieved spread being such as to permit insertion of the distal ends of legs

least one driver.

5. A tool as claimed in any one of the preceding claims, characterised in that said body (10) is a dished solid that is concentrate about said bore (11), said dished solid having a concave conical first end face at one end of said bore and a convex conical second end face at the opposite end of said bore, the connection of said at least one driver to said body (10) being such that the oscillation axis (21) is on such an alignment that, in addition to said generally radially inwardly direction, it is sloped in general accord with the respective conical slopes of said end faces.

6. A tool as claimed in claim 5, characterised in that said first end face slopes with a conical apex angle that is less than that of said second end face, and in that the oscillation axis (21) is directed inwardly at a slope that is intermediate the slopes of said end faces.

7. A tool as claimed in any one of the preceding claims, characterised in that, said collet is provided with at least two longitudinally extending finger means connected one to another at one longitudinal end, and arranged to engage an opposite longitudinal end a portion of said prosthesis, and in that coacting cam or other formations on outer zones of said fingers or on the surface of said bore are arranged to cause engagement and releasable clamping of a portion of said prosthesis member.

8. A tool as claimed in claim 7, characterised in that said body (10) has a generally cylindrical bore (11), and said coacting cam formation may comprise a frusto-conical taper of said bore, and/or a radially outwardly directed flange at said one longitudinal end of said collet, or screw means acting on said flange.

9. A radial-mode resonant device characterised in that it comprises an annular body having a central axial bore (11) and an ultrasonic driver (20) having a central axis (21) of mechanically resonant oscillation directed generally radially inwardly with respect to the central axis of said body (10) and in that said axial bore (11).

10. A collet means for use in combination with a radial-mode resonant device as claimed in claim 9, characterised in that it comprises resiliently deformable means to define an engagement zone whereby energy from said resonant device may be delivered to said prosthesis.

11. A tool for use in revision arthroplasty wherein a prosthetic member to be removed is at least partially encumbered by bone cement, characterised in that it comprises a stem (82) connected to ultrasonic transducer means, said stem (82) having a spoon shaped distal end (81) provided with apertures through which cement melted by ultrasonic vibration of said tool may pass to be removed and in that said tool is so dimensioned that it is adapted to remove cement immediately adjacent said prosthetic member.

12. A method of removing a bone-implanted prosthetic member from an installed situs of cemented or bony-ingrowth retention within a living bone, wherein at least a portion of the prosthetic is externally exposed or exposable with respect to the bone, which method comprises the steps of:

(a) selecting an annular body of a material capable of radial-mode resonant oscillation in the frequency range 20 kHz to 40kHz, said body having a central axial bore of size to accommodate an exposed portion of the prosthetic;
(b) securing the exposed portion of the prosthetic with substantially complete circumferential continuity within said bore; and
(c) ultrasonically exciting said body into radial-mode oscillation by generally radially inwardly directing mechanical-displacement energy at a peripheral location on said body, said driving energy being imparted to said body within said frequency range.

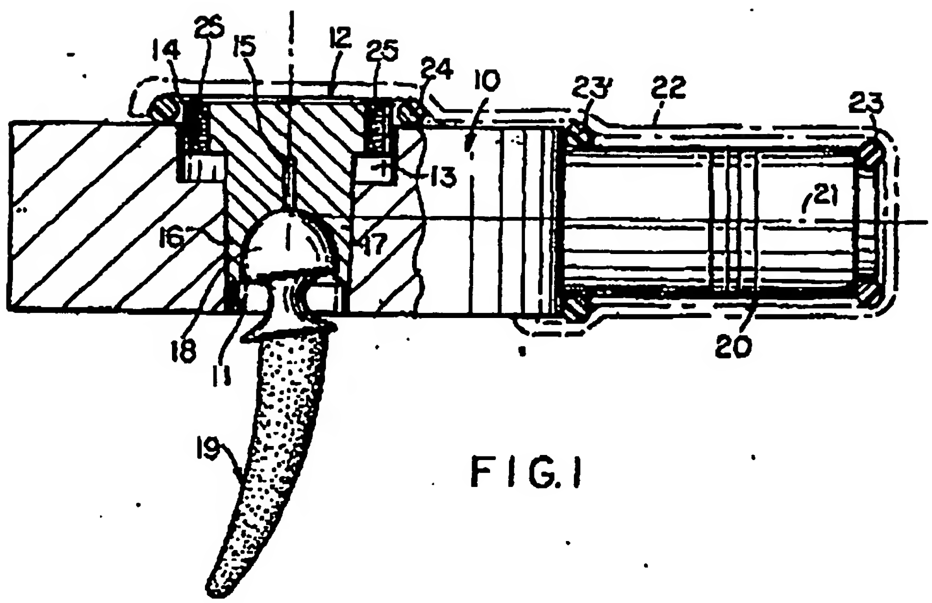
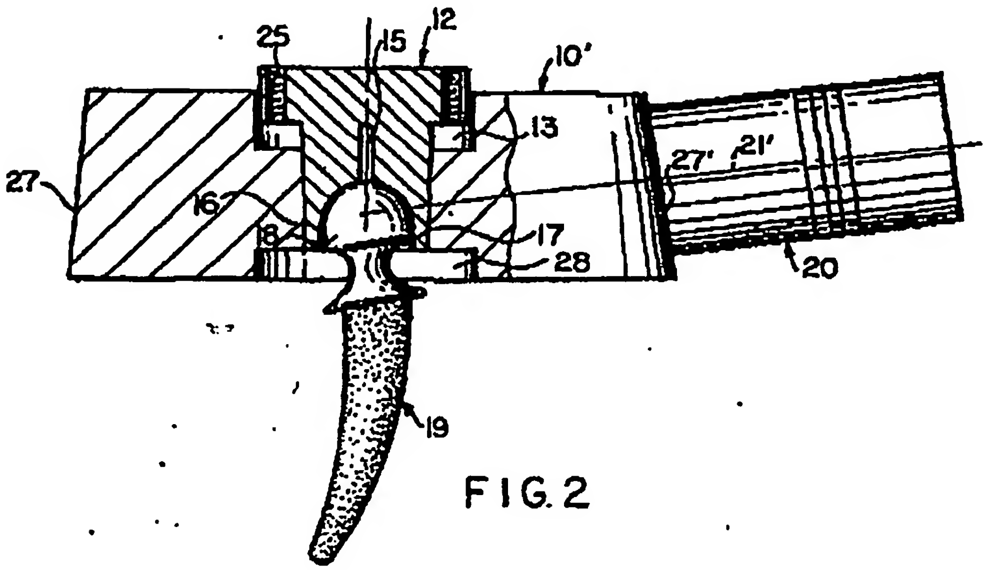

26
14
15
12
25
24
10
23'
22
23
13
21
16
17
18
11
20
19

FIG.1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15
12
10'
13
27'
21'
27
16
18
17
28
20
19

FIG.2

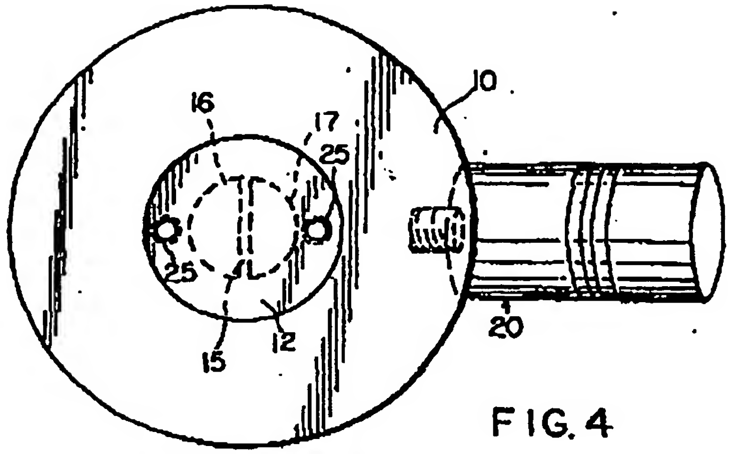

10
16
17
25
25
15
12
20

FIG. 4

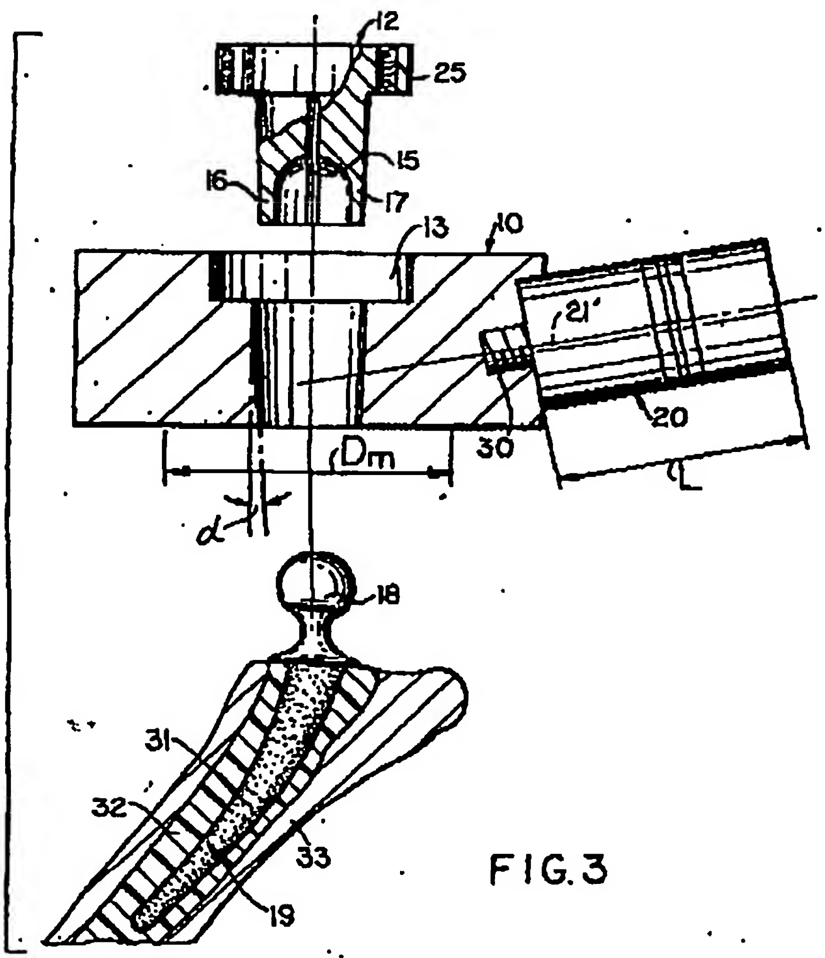

12
25
15
16
17
13
10
21'
20
30
Dm
L
α
18
31
32
33
19

FIG. 3

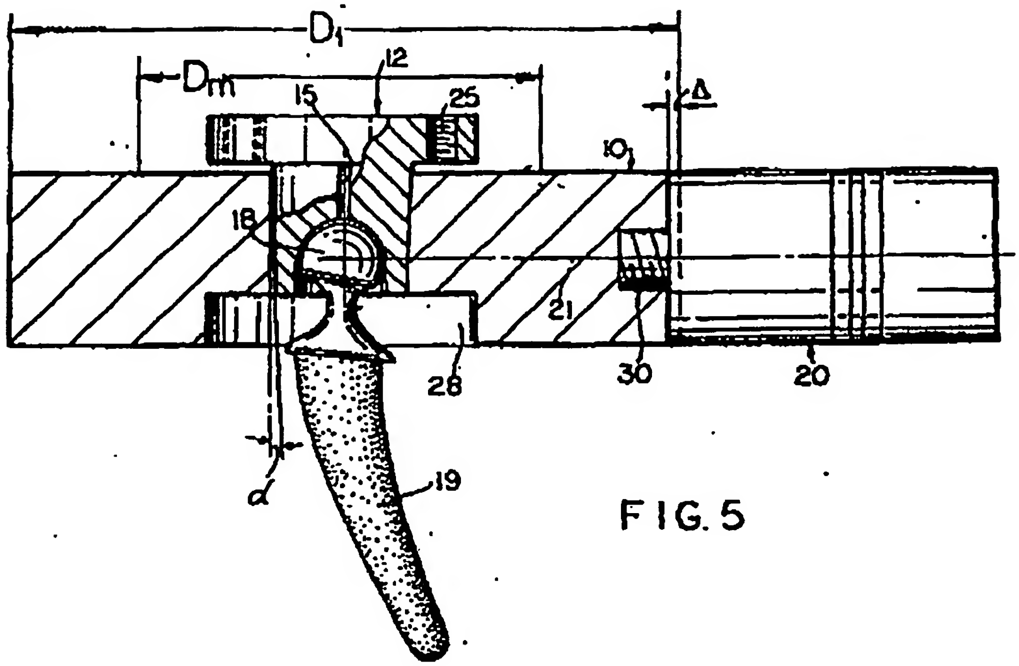

D1
Dm
12
15
25
10
Δ
18
21
28
30
20
d
19

FIG. 5

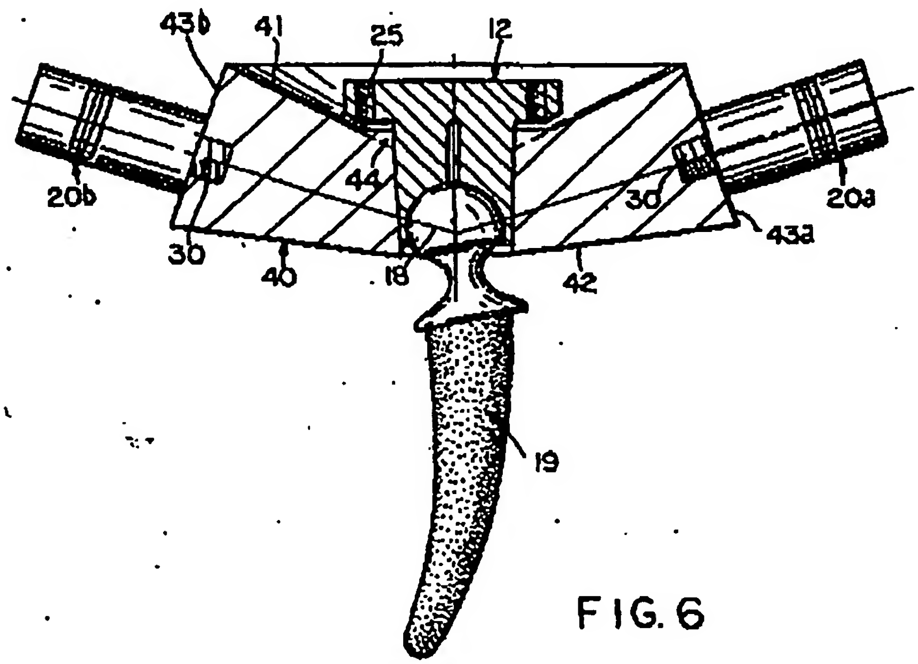

43b
41
25
12
20b
44
30
20a
43a
30
40
18
42
19

FIG. 6

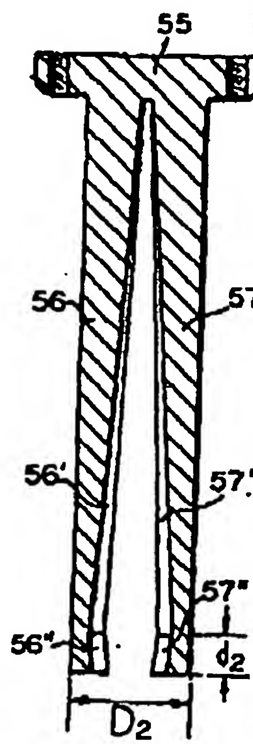


FIG.7

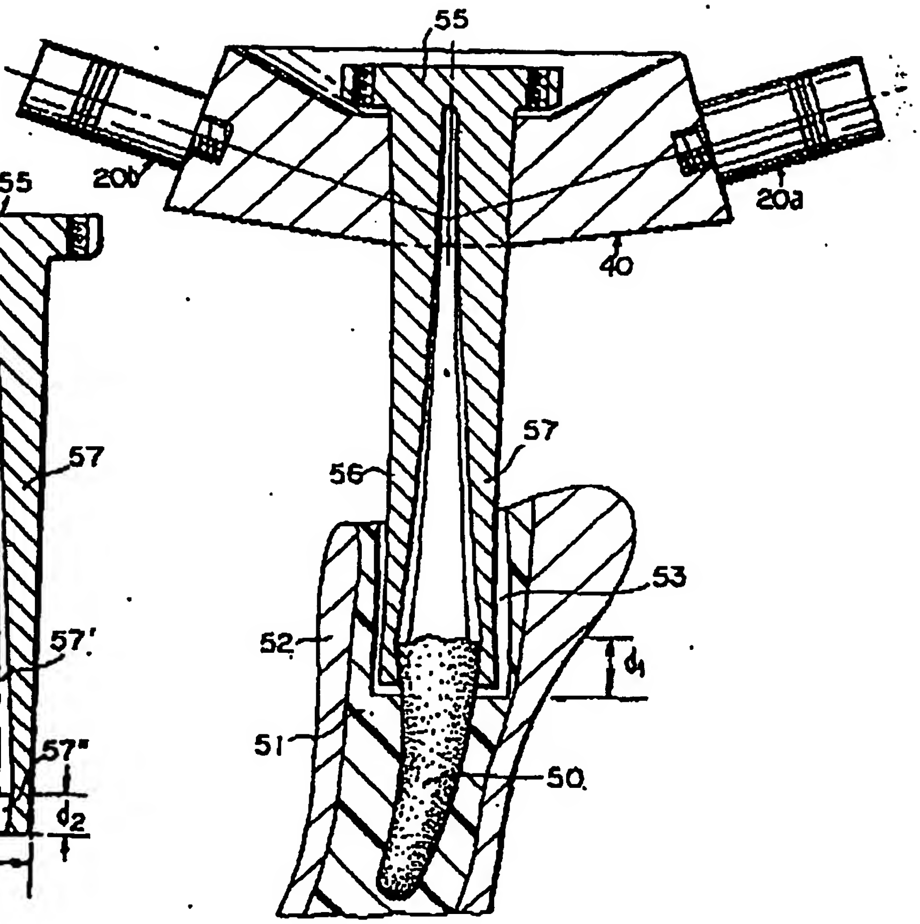
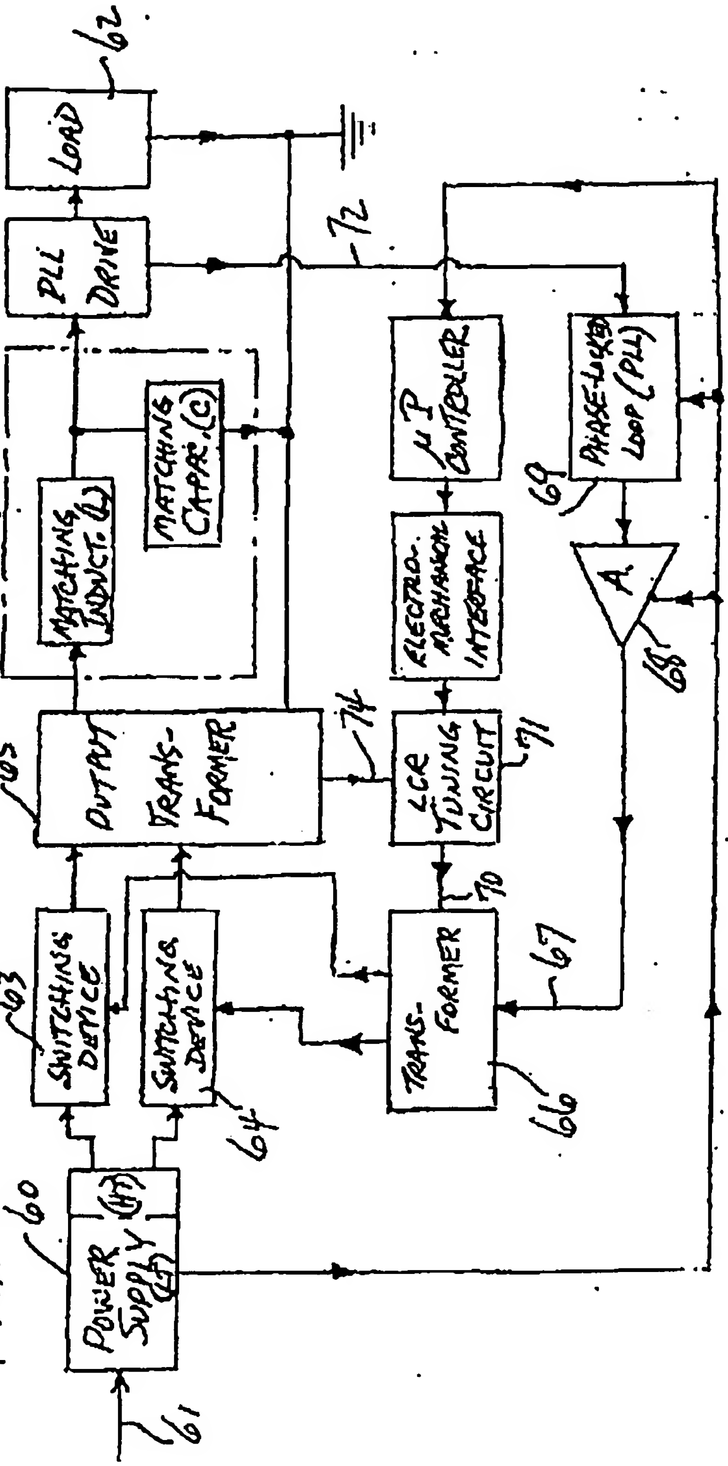


FIG.8

FIG. 9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61
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SWITCHING DEVICE
SWITCHING DEVICE
64
65
OUTPUT TRANSFORMER
73
MATCHING INDUCT. (L)
MATCHING CAPAC. (C)
PLL DRIVE
LOAD
62
72
74
TRANS-FORMER
66
67
70
LCR TUNING CIRCUIT
71
ELECTRO-MECHANICAL INTERFACE
μP CONTROLLER
PHASE-LOCKED LOOP (PLL)
69
A
68

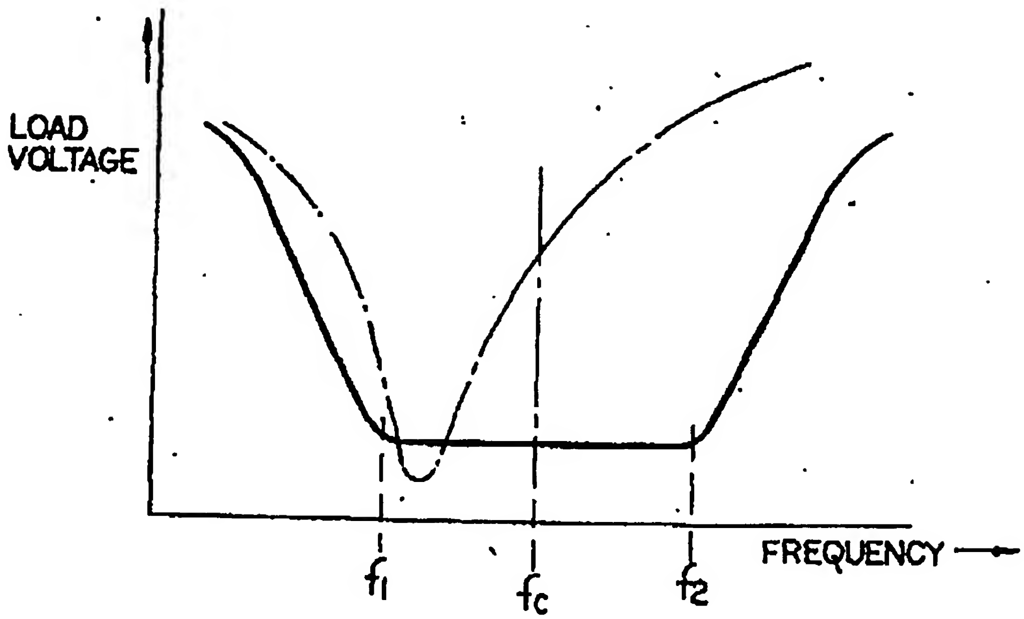

FIG. 10

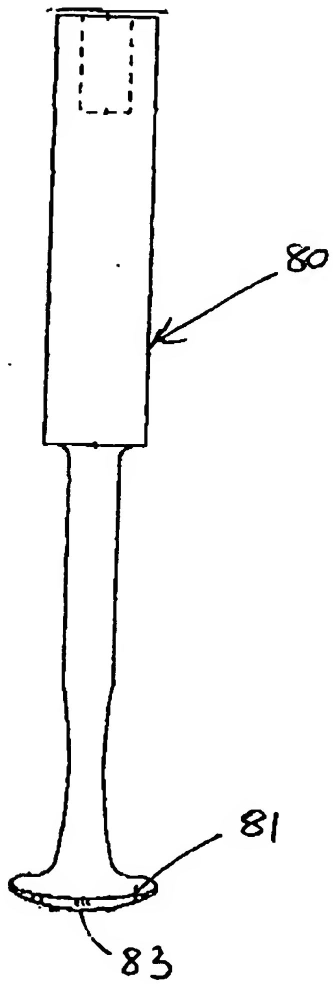

FIG 11

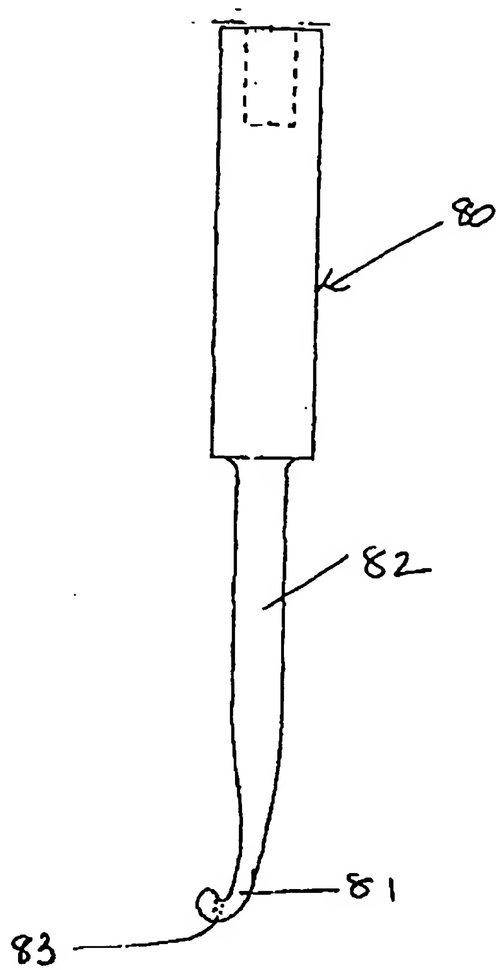

FIG 12

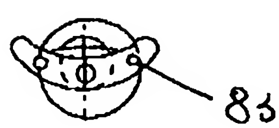

FIG13